PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Patent- und Rechtsanwälte
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13. MRZ. 2006

Bearb.: EF:
Frist:
Ablage:

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	10.03.2006
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
C5150PWO-R/Bi	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/012617	08.11.2004	07.11.2003

Applicant
CORAL LICENSING INTERNATIONAL LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Edel, M Tel. +49 89 2399-2426

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C5150PWO-R/Bi	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/012617	International filing date *(day/month/year)* 08.11.2004	Priority date *(day/month/year)* 07.11.2003
International Patent Classification (IPC) or national classification and IPC INV. A61N1/36		
Applicant CORAL LICENSING INTERNATIONAL LTD. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.09.2005	10.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Küster, G Telephone No. +49 89 2399-7240

10/578340
IAP12 Rec'd PCT/PTO 05 MAY 2006

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/012617

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

5-38	as originally filed
1-4	received on 07.09.2005 with letter of 06.09.2005

Claims, Numbers

3-14	as originally filed
1, 2	received on 07.09.2005 with letter of 06.09.2005

Drawings, Sheets

1/9-9/9	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☒ the description, pages 2
   - ☒ the claims, Nos. 1
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 8-14

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 8-14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-7
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I.

The amendments filed with the letter dated 06.09.05 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following: The wording "... adapted to vary at least one of said amplitude, said pulse repetition frequency, said duration and said offset ... from one heart cycle to the next or periodically or after a predetermined or randomly selected number or heart cycles" in amended claim 1 includes combinations that have not been disclosed in the application as originally filed.
Rather only the following combinations have been disclosed in the application as originally filed:

- variation of the amplitude: for each new heart cycle or periodically or randomly, or at predetermined time intervals (2nd para. on p. 36)
- pulse repetition frequency: from one heart cycle to the next, or after a predetermined or randomly selected number of cycles (last para. on p. 36)
- duration: none of the alternatives given in claim 1 is explicitly specified (cf. 2nd para. on p. 37)
- offset: from one heart cycle to the next, or after a predetermined or randomly selected number of heart cycles (para. bridging pages 37 and 38, i.e. no basis for "periodically").

It is noted that the passages on p. 37 l. 12-18 and p. 37 l. 25 - p. 38 l. 5 only disclose specific combinations for the interval between successive stimulation pulses, and for the offset, respectively.

This report has thus been established as if the amendments had not been made, i.e. on the basis of claim 1 as published.

Re Item III.

Claims 8-14 have not been searched (Article 17(2)(a)(I) PCT) , since they relate to subject-matter falling under Rule 39.1 (iv) PCT, in particular to methods for treatment of the human or animal body by therapy.

Re Item V.

The following documents are referred to in this communication:
D1 : WO 01/13990 A
D2 : EP 0 847 776 A
D3 : US 4 541 417 A

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** (as published, cf. Item I above) is not new in the sense of Article 33(2) PCT.

1.1 Document D1 discloses (the references in parentheses applying to this document) an electrotherapy apparatus for applying electrical stimulation to a muscle or group of muscles of a person or other mammal (2nd para. on p. 25), wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses (fig. 2B) and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal (first para. on p. 30). Said offset lies in a range from 5% of an average value of the R-R path lengths of a plurality of preceding heart cycles (2nd para. on p. 30, cf. also last para. on p. 61 with regard to heart rate measurement and 28 in fig. 4), before the predicted end of said T-wave up to 45% of an average value of the R-R path lengths of a plurality of preceding heart cycles, after the predicted end of the T-wave (2nd para. on p. 30).
The electrotherapy apparatus known from D1 is further adapted to vary at least one of said amplitude (62, cf. para. bridging p. 30 and 31), said pulse repetition frequency (60, cf. para. bridging p. 30 and 31), said duration (58, cf. 3rd para. on p. 30) and said offset (48, cf. 2nd para. on p. 29) in accordance with an adjustment by the operator (cf. also claims 20-21). The apparatus is thus suitable to vary these parameters in accordance with a predetermined pattern within pre-specified limits in the course of a treatment extending over many heart cycles, typically over more than 15 minutes (cf. also the PCT Guidelines, III-4.8).

1.2 The electrotherapy apparatus known from D2 and D3 are also regarded as suitable

for stimulation in accordance with the features defined in claim 1 of the present application, see the corresponding passages cited in the search report (see in particular col. 6 l. 19-22 in D2, and ramping amplitude in fig. 3B of D3).

2. Dependent **claims 2-7** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-D3 and the corresponding passages cited in the search report.

3. Regarding amended claim 1 as filed with the letter dated 06.09.05 it is noted that even if the claim had been restricted to those specific combinations that have been disclosed in the application as originally filed, the claim would presumably have lacked an inventive step. Attention is drawn to the document EP-A-1 136 097 cited in the search report, which describes random variation of the amplitude in order to prevent the human body from getting accustomed to the stimulation signals (col. 6 l. 58 - col. 7 l. 6). It would have been obvious for the skilled person to apply this teaching to an electrotherapy apparatus as disclosed in D1.

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IAP12 Rec'd PCT/PTO 05 MAY 2006

C5150PWO

ELECTROTHERAPY APPARATUS AND METHOD OF TREATING A PERSON OR A MAMMAL USING SUCH ELECTROTHERAPY APPARATUS

The present invention relates to electrotherapy apparatus for applying electrical stimulation to a muscle or group of muscles of a person or other mammal, wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal, said offset lying in a range from 5 % of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45 % of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave and to methods of using such electrotherapy apparatus.

Electrotherapy apparatus of the initially named kind is described in the international patent application with the publication number WO 01/13990 A1.

It has been found that this type of electrotherapy leads to extremely beneficial effects with respect to the heart of the person or mammal and, de-

pending on precisely how the electrotherapy is carried out, can also be used for curing a whole spectrum of adverse conditions.

The object of the present invention is to improve the performance of the previously described apparatus and method to provide a significant improvement in hemodynamics, i.e. the blood circulation in the body and through the heart, and in particular to prolong the length of time a treatment can be carried out without the muscles contracted by the electrostimulation loosing their responsiveness to the applied electrical stimulation by becoming accustomed to it.

In order to satisfy this object there is provided an apparatus of the initially named kind which is characterized in that the electrotherapy apparatus is adapted to vary at least one of said amplitude, said pulse repetition frequency, said duration and said offset in accordance with a predetermined pattern stored in an associated microprocessor, or randomly in accordance with a random number generator, within pre-specified limits in the course of a treatment extending over many heart cycles, typically over more than 15 minutes, and from one heart cycle to the next or periodically or after a predetermined or randomly selected number of heart cycles.

It has namely been found that by regularly changing or randomly varying the pattern of electrical stimulation applied to an electrode the muscle associated with it does not become acclimatised to the stimulation and unresponsive to it. This phenomenon is similar to the way people become accustomed to regularly repeating noises in the sense that after a while they no longer react to it or hear it. By preventing the muscles affected by electrostimulation from becoming accustomed to it their response in the sense of repeated muscle contractions can be prolonged indefinitely. Thus users with portable electrotherapy apparatus could use it for years on end with-

out the apparatus loosing its effectiveness as a result of the patients muscles becoming unresponsive.

The concept of the invention is specifically intended for counterpulsation electrotherapy where long treatment times can be particularly beneficial for the therapeutic treatment of the heart. The concept could however also be used for non-synchronised electrotherapy such as is used in many muscle toning devices and other electrotherapy apparatus.

The apparatus preferably has a plurality of output channels for applying electrical stimulations to a plurality of active electrodes provided on the person being treated.

The reason for this is as follows:

It has been found that if a muscle is subjected to contraction signals once every heart cycle, then it can become fatigued. On the other hand, the present invention is not critical with respect to the muscle to which the contraction is applied. Accordingly, it is preferable to provide a plurality of active electrodes, for example four active electrodes, which each affect a separate muscle of a group of muscles or a region of muscles on the human body. Each channel of the electrotherapy apparatus is connected to a respective one of said active electrodes. Thus, if four active electrodes are present, the first channel can be connected to the first electrode and can provide electrical stimulation for a first muscle, the second channel can be connected to a second electrode and provide electrical stimulation for a second muscle, the third channel can be connected to a third electrode and provide electrical stimulation for a third muscle, and the fourth channel can be connected to a fourth electrode and provide electrical stimulation for a fourth muscle. This means that each muscle is stimulated only

once every four heart cycles and there is therefore a rest period of three heart cycles between each electrical stimulation of any particular muscle. This avoids fatigue of the muscles.

The electrotherapy apparatus of the present invention thus applies the same electrical stimulation to each output channel in turn, each electrical stimulation comprising the initial stimulating pulses and the further stimulating pulses. Channel 1 is activated after one complete heart cycle has been detected, channel 2 is activated once a subsequent heart cycle has been detected and so on. The timing of the electrical stimulation signals applied to each channel is based on the R-R path length of the preceding heart cycle or on an average R-R path length of a plurality of preceding heart cycles. The reference in the above paragraph to the "same electrical stimulation" does not mean that the electrical stimulation applied is invariable but rather that the pattern of stimulation that is used is generally, but not necessarily used for a period of time before it is replaced with a different pattern.

This technique as described above also makes it possible to use different electro-stimulation signals, i.e. different stimulation signal shapes and values in each channel, which can also be beneficial under some circumstances.

An electrotherapy apparatus is particularly preferred in which a plurality of channel groups is provided, with each channel group comprising a plurality of channels. Each channel group preferably has the same number of channels. For example two or three channel groups can be provided and each channel group can comprise four channels.

Patent Claims

1. Electrotherapy apparatus for applying electrical stimulation to a muscle or group of muscles of a person or other mammal, wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal, said offset lying in a range from 5 % of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45 % of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave, characterised in that
the electrotherapy apparatus is adapted to vary at least one of said amplitude, said pulse repetition frequency, said duration and said offset in accordance with a predetermined pattern stored in an associated microprocessor, or randomly in accordance with a random number generator, within pre-specified limits in the course of a treatment extending over many heart cycles, typically over more than 15 minutes, and from one heart cycle to the next or periodically or after a predetermined or randomly selected number of heart cycles.

2. Electrotherapy apparatus in accordance with claim 1, characterised in that
said amplitude variation can amount to a variation in peak voltage of said electrical stimulating pulses in a range from +1 or -1 V to +10 or -10 V from a nominal value selected in the range from typically 10 to 50 V.